



A Code of Practice for the Production of Human-derived Therapeutic Products

This document has no statutory force and should not be regarded as an interpretation of any Act, Regulation or Directive. Compliance with this Code of Practice does not itself confer immunity from any legal obligations.

This Code of Practice will be reviewed not later than June 2006.

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Glossary

For the purposes of this document the following definitions apply:

Adverse incident

An event where death or serious injury or unexpected event occurs.

Allogeneic use

Cells or tissues transplanted from one person to another.

Ancillary materials

Any item that is in contact with the tissue during processing.

Autologous use

Cells or tissues removed from and transplanted back to the same person.

Biomaterial

Natural or synthetic materials, including polymers, ceramics and collagen matrix, that may be used as a scaffold.

Cell culture

The maintenance of cells *in vitro*.

Cells

Individual cells or collection of cells that are not bound by any form of connective tissue.

Cell expansion

Increasing the quantity of cells by their replication *in vitro*.

Cell line

A well characterised culture that has been demonstrated to be phenotypically and genotypically consistent over a specified number of population doublings.

Clinical effectiveness

The ability to produce a specific clinical result, exert a specific measurable clinical influence or produce a desired beneficial clinical effect in actual use.

Clinical performance

The ability to exhibit a specific property or function in actual use.

Confirmatory tests

A series of tests conducted on a repeat reactive sample by a designated reference laboratory to confirm the true or false nature of the repeat reactivity observed in the screening laboratory.

Continuous cell lines

A cell line that appears to have the capacity for indefinite replication.

Cross-contamination

Contamination of cells or tissues with other cells or tissues and contamination between production staff and the product.

Disinfection

Treatment which reduces the numbers of bacteria, fungi and some viruses.

Donor

A living or a recently deceased person from whom tissues or cells have been removed.

Finite cell line

A cell line that can be maintained for a limited number of population doublings and ultimately loses the ability to replicate.